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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,526	02/26/2004	C. Allen Chang	3102/2020	6448
35743 7590 03/01/2007 KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/01/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/01/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary

Application No.

10/787,526

Applicant(s)

CHANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-9,11,12 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9 and 17 is/are rejected.
- 7) ☒ Claim(s) 11, 12, 15, 16, and 18-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 1/23/07 wherein claims 1, 3, 4, 7-9, and 11 are amended and claims 2, 5, 6, 10, 13, 14, and 21-46 are canceled.

Note: Claims 1, 3, 4, 7-9, 11, 12, and 15-20 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments and/or amendment filed 1/23/07 to the rejection of the claims made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive because Applicant has amended the claims to overcome the rejections. Therefore, the said rejection is hereby withdrawn. However, the amended claims deemed necessary the following rejections.

112 SECOND PARAGRAPH REJECTIONS

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 4, 7-9, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 7, and 8: The claims as written are ambiguous because independent claim 1 is directed to an excipient having the formula $X_m[X'L']^n$ wherein X and X' are calcium and L' is an organic ligand. Thus, the amending of the claim (see

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lines 5-7) to state that the variable L' is an organic ligand which may be 'the same as the organic ligand of the metal chelate contrast agent or may be another organic ligand...contrast agent' is confusing. In particular, independent claim 1 is confusing because the excipient only comprise calcium and an organic ligand, L', thus, references to components not present in the excipient confuses the claims. It should be noted that in independent claim 1, it is the excipient, not the metal chelate contrast agent, that is being claimed. The metal chelate contrast agent is the intended use of the excipient. Applicant is reminded that for a product claim, patentability is based upon the components of the product, not the intended utility of the product. The utility of a product is claimed in a method of use claim, not a product claim. Hence, since claims 3, 4, 7, and 8 depend upon claim 1 for which one cannot clearly ascertain what is being claimed, those claims are also ambiguous.

Note: Applicant is respectfully requested to review claims 3, 4, 7, and 8 and make the appropriate corrections to the phrase 'the organic ligand of the metal chelate contrast agent' to be consistent with the components for the excipient only (the excipient is the product which is being claimed in independent claim 1).

Claims 9 and 17: Independent claim 9 is ambiguous because it is unclear what metal chelate contrast agent Applicant is referring to in the claims. The claim is directed to a contrast agent comprising a metal. Therefore, referring to an organic ligand which may be the same as the organic ligand of the metal chelate contrast agent is confusing. What metal chelate is Applicant referring to? One cannot have a metal chelate contrast agent in a claim wherein the contrast agent is being claimed because the contrast agent

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is one component of a metal chelating agent, so how can one claim a contrast agent at the beginning of a claim and near the claim disclose that the metal chelate contrast agent organic ligand is that of the contrast agent? Thus, is it difficult to ascertain exactly what is being claimed. Claim 17 is also ambiguous because it depends upon independent claim 9 which is ambiguous and makes reference to the metal chelate contrast agent.

CLAIM OBJECTIONS

5. Claims 11, 12, 15, 16, and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLARIFICATION OF RECORD

6. It should be noted that while the claims are allowable over the prior art of record, this is for Applicant's elected Group I which is directed to excipients and metal chelates herein L and L' are independently selected from those encompassed by the formula of claim 4. Thus, Applicant is respectfully requested to incorporate the formula of claim 4 into the dependent claims. This is the Group which Applicant elected to prosecute.

COMMENTS/NOTES

7. It is once again noted that no prior art has been cited against the claims. The claims are distinguished over the prior art of record for reasons of record in the office action mailed 11/1/06. However, Applicant MUST address and overcome the 112 rejections above.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'D. L. Jones', is written over the printed name.

D. L. Jones
Primary Examiner
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February 16, 2007